

### **REMARKS/ARGUMENTS**

Claims 1-2 and 5-20 are pending in the application. Reconsideration and allowance of all pending claims are respectfully requested.

On page 2 of the Office Action the Examiner maintained the rejection of claims 1-2, 5-9 and 15 under 35 U.S.C. § 103(a) as being unpatentable over WO 99/53777 (“the ‘777 reference”) in view of DeVries et al., U.S. Pat. No. 6,495,177 (“deVries et al.”). The applicants respectfully traverse the rejection. Claim 1 recites a non-chewable pharmaceutical or dietary composition consisting of (a) one or more vitamins, (b) one or more minerals selected from the group consisting of Iron, Zinc and Magnesium, (c) one or more trace elements selected from the group consisting of Chromium, Copper, Iodine, Molybdenum and Selenium, (d) docosahexaenoic acid (DHA), and (e) a pharmaceutically or dietetically suitable carrier. Rejected claim 1 does not include calcium.

The applicants submit that combining the references as proposed in the Office Action to arrive at the invention of rejected claim 1 (*i.e.*, a supplement that cannot contain calcium) changes the principle of operation of the ‘777 reference being modified and renders the ‘777 reference unsatisfactory for its intended purpose. Therefore, the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959). The Examiner alleges that the “‘777 reference discloses a composition comprising the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium [and others]”, such that calcium is just one of many recommended minerals that could be added to the composition. The applicants submit this is not the case because one of the main thrusts of the ‘777 reference is to provide calcium without having to ingest dairy products:

Calcium is among the nutrients the recommended levels of which is increased proportionately more than that of energy and other nutrients during pregnancy and lactation and taking extra milk or dairy products will normally provide additional calcium. . . . In particular lactose intolerant individuals need an alternative calcium source which contains no lactose. . . . It is an object of the present invention to provide a nutritional composition which supplies the extra-needs of essential nutrients for pregnant and lactating women and which is lactose-free and which is essentially free of milk products and is, therefore, suitable for women who are lactose intolerant and women expecting a baby with an increased risk of developing cow’s milk allergy because of i.a. a family history of allergies (pages 1 to 2 of the ‘777 reference).

The Examiner further alleges that the “[a]pplicant is emphasizing the preferred embodiments of the references cited in the arguments”. By the above disclosure in the ‘777 reference, it is clear that calcium is not only one of the many recommended vitamins and minerals but is an essential ingredient to the composition if it is to work as the inventors wanted. Therefore, by its own disclosure, the principle of operation of the ‘777 reference is to provide a supplement of calcium to the intended recipients.

The invention of deVries et al. stresses the importance of the **exclusion** of calcium. Combining the references as proposed in the Office Action to arrive at the invention of rejected claim 1 (*i.e.*, a supplement that cannot contain calcium) changes the principle of operation of the ‘777 reference being modified, and renders the ‘777 reference unsatisfactory for its intended purpose (*i.e.*, a composition that contains calcium but does not include dairy products), and thus the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959). Therefore, claim 1 is not obvious over the ‘777 reference in view of deVries et al. and is thus allowable. Claims 2, 5-9 and 15 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

On page 5 the Examiner maintained the rejection of claims 10-13 and 16-20 under 35 U.S.C. § 103(a) over the ‘777 reference in view of deVries et al. and further in view of Uiterwaal et al., U.S. Pat. No. 4,710,387 (“Uiterwaal et al.”). The applicants respectfully traverse the rejection. For the same reason above, the combination of the ‘777 reference and deVries et al. does not result in the invention of rejected claim 10. Uiterwaal et al. fails to cure the deficiencies of the ‘777 reference and deVries et al. Rejected claim 10 recites a non-chewable solid dosage form pharmaceutical or dietary composition consisting of (a) a multi-vitamin mixture consisting of β-carotene, Vitamin B<sub>1</sub>, Vitamin B<sub>2</sub>, Vitamin B<sub>6</sub>, Vitamin B<sub>12</sub>, Vitamin C, Vitamin D<sub>3</sub>, Vitamin E, Folic Acid, Biotin and Niacinamide; (b) a mineral mixture consisting of Iron, Zinc and Magnesium ; (c) a mixture of trace elements consisting of Chromium, Copper, Iodine, Molybdenum and Selenium; (d) docosahexaenoic acid; and (e) a pharmaceutically or dietetically suitable carrier. Uiterwaal et al. teaches a nutritional supplement containing calcium for pregnant and breast feeding women. Uiterwaal et al. does not provide any reason for a skilled artisan to exclude calcium, and even if a skilled artisan were to do so, the principle of

operation of the '777 reference would be changed thus resulting in the teachings of the references as not sufficient to render the rejected claims *prima facie* obvious. Therefore, claim 10 is not obvious over the '777 reference in view of deVries et al. and further in view of Uiterwaal et al. and is thus allowable. Claims 11-13 and 16-20 which depend from claim 10 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

On page 7 the Examiner maintained the rejection of claim 14 under 35 U.S.C. § 103(a) over the '777 reference in view of deVries et al. and further in view of Uiterwaal et al. and Jimerson, Drug Development and Industrial Pharmacy, 12(8&9): 1133-1144 (1986) ("Jimerson"). The applicants respectfully traverse the rejection. Rejected claim 14 depends from claim 10 and recites further features. Jimerson only discloses a soft gelatine capsule and provides no reason for a skilled artisan to include or exclude calcium in a nutritional supplement. Jimerson does not cure the deficiency recited above with respect to claim 10, therefore, claim 14 is not obvious over the '777 reference in view of deVries et al. and further in view of Uiterwaal et al. and Jimerson and is thus allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

In view of the foregoing remarks, the applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fee for a RCE is included herewith. In the event that there are any fees dues and owing in connection with this matter, please charge the same to our Deposit Account No. 11-0223.

Respectfully submitted,

Dated: November 18, 2008

By: s/Timothy X. Gibson/  
Timothy X. Gibson  
Reg. No. 40,618  
Attorney for Applicant(s)

Patent Department  
Boehringer Ingelheim Corp.  
900 Ridgebury Road  
P.O. Box 368  
Ridgefield, CT 06877  
Tel.: (203) 798-4868